K023957

DEC 13 2002

510(K) Summary Of Safety And Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official: Michael A. Hoffman
Director – Quality Assurance and Regulatory Affairs
E-mail: michael.hoffman@sonosite.com
Telephone: (425) 951-1297
Facsimile: (425) 951-1201
Date prepared: November 13, 2002

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite hand-carried ultrasound system (C2 Series) *(subject to change)*

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving And Communications System	892.2050	90-LLZ

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite hand-carried ultrasound system (K014116), (K010374) and the Philips Ultrasound HDI® 5000 Ultrasound System (K011224). Where applicable, this new Submission references sections of K014116 and K010374 to signify that the sections remain the same as for those predicate devices.

4) Device Description:

The SonoSite hand-carried ultrasound system, C2 Series is a highly portable, software controlled ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, Velocity Color Doppler (VCD) and Directional Color Power Doppler, or in a combination of these modes.

The System has an electrocardiography (ECG) display feature and supports a 3-lead ECG cable assembly to collect data for M-mode measurements. The System provides measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The System has a PW and CW Doppler audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The system includes Digital Imaging and Communications (DICOM) to capabilities to provide the acceptance, transfer, display, storage, and digital processing of ultrasound images.

The SonoSite hand-carried ultrasound system (C2 Series) is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	**2.0 - 10.0 MHz**
Transducer Types:	Linear array Curved array Intracavitary array Static probes

The SonoSite hand-carried ultrasound system (C2 Series) is designed to comply with the standards listed below.

a. ANSI/AAMI EC 53: 1995 + Amendments, ECG Cables and Electrodes except for sections 4.4 and 4.5.9.
b. CAN/CSA-C22.2, No. 601.1:1998, Canadian Standards Association, Medical Electrical Equipment-Part 1. General Requirements for Safety
c. EN 60529, European Norm, Degrees of Protection Provided by Enclosures (I.P. Code)
d. EN 60601-1:1997, European Norm, Medical Electrical Equipment-Part 1. General Requirements for Safety
e. EN 60601-1-1:1993, European Norm, Medical Electrical Equipment – Part 1. General Requirements for Safety-Section 1-1. Collateral Standard. Safety Requirements for Medical Electrical Systems

f. EN 60601-1-2:2001, European Norm, Medical Electrical Equipment. General Requirements for Safety-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests, Second Edition
g. EN 60601-2-25:1996, European Norm, Medical Electrical Equipment-Part 2. Particular Requirements for Safety-Section 25. Specification for Electrocardiographs
h. IEC 61157:1992, International Electrotechnical Commission, Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment
i. ISO 10993 Biological Evaluation of Medical Devices and Related Tests
j. JIS-T-100x Series, Japanese Standards for Medical Electrical Equipment
k. Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994
l. NEMA PS3.15 2000, Digital Imaging and Communications in Medicine (DICOM) Part 15: Security Profile.
m. NEMA UD2-1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
n. NEMA UD3-1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
o. RTCA/DO160D:1997, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B
p. UL 2601-1:1999, Underwriters Laboratories, Inc., Medical Electrical Equipment-Part 1: General Requirements for Safety
q. UL 94, Fifth Edition, Underwriters Laboratory, Inc., Tests for Flammability of Plastic Materials for Parts in Devices and Appliances

5) Intended Use:

The intended uses of the SonoSite hand-carried ultrasound system (C2 Series), as defined by FDA guidance documents, are:

Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative (Abdominal organs and vascular)	Trans-urethral
Laparoscopic	Musculo-skel. (Conventional)
Pediatric	Musculo-skel. (Superficial)
Small Organ (breast, thyroid, testicles.)	Cardiac Adult
Neonatal Cephalic	Cardiac Pediatric
Adult Cephalic	Peripheral vessel

Typical examinations performed using the SonoSite hand-carried ultrasound system (C2 Series) are:

Abdominal Imaging Applications:

This system transmits ultrasound energy into the abdomen of patients using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Cardiac Imaging Applications:

This system transmits ultrasound energy into the thorax of patients using 2D, M-mode, directional color power Doppler (DCPD), velocity color Doppler (VCD), color Doppler, Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size can be assessed for the presence or absence of pathology. The heart can be imaged trans-thoracic. The patient's electrocardiogram (ECG) may be obtained and is used for accurate timing of diastolic and systolic function.

Warning:	The ECG is not used to diagnose cardiac arrhythmias and is not designed for long term cardiac rhythm monitoring.

Cephalic Imaging Applications:

This system transmits ultrasound energy into the heads of adults and neonates using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The patient's blood flow can be evaluated transcranially.

Gynecology and Infertility Imaging Applications:

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally.

Interventional and Intraoperative Imaging Applications:

This system transmit ultrasound energy into the various parts of the body using 2D, color power Doppler (CPD), directional color power Doppler (DCPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images that provide guidance during interventional and intraoperative procedures. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, ova harvesting, amniocentesis and other obstetrical procedures, and provide assistance during abdominal and vascular intraoperative procedures.

Obstetrical Imaging Applications:

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), color Doppler, Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology trans-abdominally or trans-vaginally. CPD and DCPD imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

Warning:	CPD or DCPD images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Pediatric and Neonatal Imaging Applications:

This system transmits ultrasound energy into the pediatric or neonatal patients using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), pulsed wave (PW) and continuous wave (CW) Doppler to obtain ultrasound images. The pediatric abdominal, pelvic and cardiac anatomy, pediatric hips, neonatal heads, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Prostate Imaging Applications:

This system transmits ultrasound energy into the prostate of an adult male using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The prostate gland can be assessed for the presence or absence of pathology transrectally.

Superficial Imaging Applications:

This system transmits ultrasound energy into various parts of the body using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Vascular Imaging Applications:

This system transmits ultrasound energy into the various parts of the body using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The carotid arteries, deep veins in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs can be assessed for the presence or absence of pathology.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, CW Doppler, velocity color Doppler, Color Power Doppler, and directional color power Doppler, and duplex imaging) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA, 1998) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All applications:

I_{SPTA} (d)	720 mW/cm^2 (Maximum)
TIS/TIB/TIC	0.1 - 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 - 700 W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

SonoSite, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K023957
Trade Name: SonoSite Hand-carried Ultrasound System (C2 Series)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: November 26, 2002
Received: November 27, 2002

Dear Mr. Job

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Hand-carried Ultrasound System, as described in your premarket notification:

Transducer Model Number

C11/7-4 7.0-4.0 MHz Curved Array
C11e/10-5 10.0–5.0 MHz Curved Array

C15/4-2 4.0–2.0 MHz Curved Array
C60/5-2 5.0-2.0 MHz Curved Array
HST/10-5 10.0-5.0 MHz Linear Array
ICT/7-4 7.0-4.0 MHz Intracavitary
C8/8-5 8.0-5.0 MHz Prostate
ICTe/10-5 10.0 -5.0 MHz Intracavitary
L25/10-5 10.0-5.0 MHz Linear Array
L38/10-5 10.0-5.0 MHz Intracavitary
L52/10-5 and L52S/10-5 10.0-5.0 MHz Linear Array
2.0 MHz Dual Element Circular Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K023957

Table 1- Diagnostic Ultrasound Indications for Use Form – C2 System

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	N/A
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Abdominal	P	P	P	P	N	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P	P	N	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Neonatal Cephalic	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Adult Cephalic	N	N	N		N	**B+M; B+PWD; B+CD**	Note 1
	Trans-rectal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Trans-vaginal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	N	B+M; B+PWD; B+CWD; **B+CD**	Note 1
Cardiac	Cardiac Pediatric	P	P	P	P	N	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

Indications for Use

David G. Hegyum

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023957

Section 4.3

K023957

Table 2 - Diagnostic Ultrasound Indications for Use Form - C11/7-4 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	C11/7-4 7.0 – 4.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023957

K023957

Table 3 - Diagnostic Ultrasound Indications for Use Form - C11e/10-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	C11e/10-5 10.0 – 5.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023957

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Table 4 - Diagnostic Ultrasound Indications for Use Form - C15/4-2 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	C15/4-2 4.0 – 2.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric	P	P	P			B+M; B+PWD	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P			B+M; B+PWD	Note 1
	Neonatal Cephalic	P	P	P			B+M; B+PWD	Note 1
	Adult Cephalic	**N**	**N**	**N**		**N**	**B+M; B+PWD; B+CD**	**Note 1**
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
Cardiac	Cardiac Pediatric	P	P	P	P	**N**	B+M; B+PWD; B+CWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023957

K023957

Table 5 - Diagnostic Ultrasound Indications for Use Form - C60/5-2 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	C60/5-2 5.0-2.0 MHz Curved Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Abdominal	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
Cardiac	Cardiac Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023457

Table 6 - Diagnostic Ultrasound Indications for Use Form – HST/10-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	HST/10-5 10.0-5.0 MHz Linear Array Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)	E	E	E		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric	E	E	E		N	B+M; B+PWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)	E	E	E		N	B+M; B+PWD; **B+CD**	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	E	E	E		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	E	E	E		N	B+M; B+PWD; **B+CD**	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 7 - Diagnostic Ultrasound Indications for Use Form – ICT/7-4 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	ICT/7-4 7.0-4.0 MHz Intracavitary Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Trans-vaginal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 8 - Diagnostic Ultrasound Indications for Use Form – C8/8-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	C8/8-5 8.0- 5.0 MHz Prostate Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging & Other	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Trans-vaginal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 9 - Diagnostic Ultrasound Indications for Use Form – ICTe/10-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	ICTe/10-5 10.0- 5.0 MHz Intracavitary Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Trans-vaginal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 10 - Diagnostic Ultrasound Indications for Use Form – L25/10-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	L25/10-5 10.0-5.0 MHz Linear Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Neonatal Cephalic	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		N	B+M; B+PWD; **B+CD**	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 11 - Diagnostic Ultrasound Indications for Use Form - L38/10-5 Transducer

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	L38/10-5 10.0- 5.0 MHz Intracavitary Transducer
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Neonatal Cephalic	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 12 - Diagnostic Ultrasound Indications for Use Form – L52/10-5 & L52-S/10-5 Transducers

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	L52/10-5 and L52S/10-5 10.0-5.0 MHz Linear Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal	P	P	P			B+M; B+PWD	Note 1
	Abdominal	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-operative (Abdominal organs and vascular)	P	P	P			B+M; B+PWD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic	P	P	P			B+M; B+PWD	Note 1
& Other	Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Small Organ (breast, thyroid, testicles.)	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Neonatal Cephalic	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P			B+M; B+PWD	Note 1
	Musculo-skel. (Superfic.)	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel	P	P	P		**N**	B+M; B+PWD; **B+CD**	Note 1
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K014116. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K023957

K023957

Table 13 - Diagnostic Ultrasound Indications for Use Form - 2 MHz Doppler Pencil

System:	SonoSite hand-carried ultrasound system, version C2
Transducer:	Doppler Pencil Transducer 2.0 MHz Dual Element Circular Array
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic							
& Other	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
	Cardiac Adult				N			
Cardiac	Cardiac Pediatric				N			
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral	Peripheral vessel							
Vessel	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Prescription Use (Per 21 CFR 801.109)

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